OMB No. 0990-0115

Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE http://www.niaid.nih.gov/contract/default.htm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.

RFP Number:	**Just In Time:**	**Small Bus. Set-Aside:** [ ]Yes [X]No 8(a) Set-Aside [ ]Yes [X]No NAICS Code: 541710 Size Standard: 500 employees	**Level of Effort**: [ ] Yes [X] No Total Effort: [N/A]
NIH-NIAID-DAIDS-03-02	[ ] Yes [X] No		

TITLE:
Primate Core Immunology-Virology Laboratories

Issue Date: August 2, 2002	**Due Date: October 30, 2002** **Time: 4:00 PM, EST**	**Technical Proposal Page Limits:** [X] Yes -75 Pages *(see "How to Prepare and Submit Electronic Proposals")*

ISSUED BY:

Jacqueline C. Holden
Contracting Officer
Contract Management Branch, DEA
NIH, NIAID
6700-B Rockledge Drive
Room 2230, MSC 7612
Bethesda, MD 20892-7612

[X] ***We reserve the right to make awards without discussion.***

NO. OF AWARDS:

[ ] Only 1 Award
[X] Multiple Awards

PERIOD OF PERFORMANCE:

7 years beginning on or about 06/30/2003

Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

POINT OF CONTACT **-- Lois Eaton** ***--COLLECT CALLS WILL NOT BE ACCEPTED--***

Telephone: ***Direct*** **301-496-0611** ***Main*** **301-496-0612**	***Fax*** **301-402-0972**	***E-Mail*** **le52u@nih.gov**

Updated thru FAC 97-25 (05/02/01)

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Background
Primate Core Immunology-Virology Laboratories
DAIDS-03-02

This RFP is entitled "**Primate Core Immunology - Virology Laboratories**." This RFP solicits proposals for laboratories to support the vaccine and prevention research program of the Preclinical Research and Development Branch, DAIDS. The Government has a need to continue this effort and expand laboratory support as part of the AIDS vaccine research agenda. The Primate Core Immunology and Virology Laboratories will provide resources in support of AIDS vaccine studies in non-human primates by conducting standardized assays to assess cellular and humoral immune responses of nonhuman primates to HIV and SIV vaccines and will also measure viral replication levels in the animals after viral infection. The new Primate Core Immunology-Virology Laboratories also will serve as Reference Laboratories for Quality Assurance and Quality Control of immune and virology-based assays, to aid in the standardization of assays across the non-human primate AIDS research field.

The demonstration of protection from infection or the reduction in virus load and the slowing of disease progression by SIV and HIV vaccines in primates has led to cautious optimism for the successful development of a protective vaccine against HIV/AIDS. To translate the findings from vaccine studies in primates into an effective HIV vaccine for people, it is essential to understand which immune responses provide protection, how to enhance and prolong those responses, and to identify the viral antigens against which effective immune responses are directed. These objectives require accurate, sensitive, and reproducible immunological and virological assays conducted in laboratories with appropriate experience and expertise. The comparison of the effectiveness of vaccines also requires that assays be conducted by a centralized laboratory or by investigators using assays that have been shown to be equivalent to those conducted at the centralized laboratory. Evaluations of cellular immune responses and neutralizing antibody responses are currently being conducted at the Primate Core Immunology Laboratory, which conducts assays for cellular immune responses in Dr. Norman Letvin's laboratory at Beth Israel Hospital, Harvard University, and neutralizing antibody assays at Dr. David Montifiori's laboratory at Duke University. The current contracts do not cover the evaluation of viral load post challenge. However, the development of accurate, quantitative assays for the measurement of levels of viral RNA in the plasma of infected non-human primates makes a core virology laboratory essential. This capability will be added as a third component of the laboratory assay support for non-human primate AIDS vaccine studies. In addition, in the new contract(s) for the cellular and humoral immunology laboratories, added emphasis will be placed on the adaptation of assays to assess mucosal immune responses. The new Primate Core Immunology-Virology Laboratories also will serve as Reference Laboratories for Quality Assurance and Quality Control of immune- and virology-based assays, to aid in the standardization of assays across the non-human primate AIDS research field , and will provide standardized reagents and methods to outside laboratories. The Laboratories will provide support to the DAIDS-supported Simian Vaccine Evaluation Units and grantees, and other laboratories as requested by the Project Officer.

In summary, the Primate Core Immunology-Virology Laboratories will provide resources in support of AIDS vaccine studies conducted in non-human primates at NIAID's Simian Vaccine Evaluation Units. They also will be available to provide immunological and virological support for vaccine studies conducted by NIAID grantees, as contract personnel and resources allow, requested by the Project Officer.

The Laboratories will:

Conduct assays to assess cellular immune responses,
Conduct assays to evaluate neutralizing antibodies,
Conduct assays to measure plasma virus levels

Separate proposals are solicited for separate parts of this solicitation: a bacterial respiratory pathogens reference laboratory and a viral respiratory reference laboratory.

The three Parts are:

PART A - Cellular Immunology Laboratory - will focus on the conduct of assays for viral (SIV, HIV, SHIV) antigen-specific cellular immune responses, such as ELISPOT, Intracellular Cytokine Staining, CTL, and T cell proliferation assays.

PART B - Humoral Immunology Laboratory - will focus on the conduct of viral (SIV, HIV, and SHIV) neutralization assays, with an increasing focus on assays able to assess the ability of sera to neutralize infection with primary isolates of HIV-1.

PART C - Quantitative Viral RNA Laboratory - will focus on the conduct of assays to quantitatively measure, with a high degree of sensitivity and accuracy, the plasma levels of SIV, SHIV, or HIV viral RNA in infected non-human primates.

AN OFFEROR MAY RESPOND TO EITHER PART A, PART B, OR BOTH, BUT IS ADVISED THAT EACH PART MUST BE SUBMITTED AS A SEPARATE PROPOSAL. It is anticipated that three (3) to four (4) contracts will be awarded to successful Offerors demonstrating capability of responding to the requirements of this solicitation. Negotiations will take place with Offerors whose proposals are determined to be in the competitive range. If Part A, Part B, and Part C from a single Offeror are in the competitive range, the government reserves the right to negotiate a single contract and the Offeror's Statement of Work will comprise all of the relevant Parts of the award.

STATEMENT OF WORK:
PART A: CELLULAR IMMUNOLOGY LABORATORY

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to provide a Primate Immunology Laboratory that shall support the evaluation of prototype AIDS vaccines in primates in studies conducted at several institutions under the sponsorship of the Division of AIDS, NIAID, NIH, with emphasis on studies conducted at Simian Vaccine Evaluation Unit (SVEU) contract sites.

Specifically, the Contractor shall:

1. Evaluate and characterize the cellular immune responses of nonhuman primates that have been immunized with HIV or SIV vaccines and/or infected with HIV, SHIV, or SIV. Assays to be conducted are to include, but are not to be limited to, those described below:

    a. Perform assays to detect HIV or SIV antigen-specific cytotoxic CD8+ T lymphocytes (CTLs) in nonhuman primates immunized with HIVor SIV vaccines and/or infected with HIV, SHIV, or SIV.

        1) Receive/obtain peripheral blood cells from the animals in a vaccine study being conducted at a Simian Vaccine Evaluation Unit (SVEU) site or by other investigators, as requested by the Project Officer, and establish transformed B lymphoblastoid cell lines for use as stimulator cells and/or target cells in CTL assays. Freeze a stock of each transformed cell line. Maintain the transformed B cell lines for use in CTL assays during the course of the study.

        2) Perform SIV or HIV antigen-specific (as required by the study protocol) *in vitro* stimulation and expansion of SIV- or HIV- specific CTL precursors from immunized and/or infected animals to generate specific T cell responses.

        3) Perform assays to detect CTL activity directed against SIV or HIV epitopes (as required by the study protocol) in immunized nonhuman primates, and in nonhuman primates after virus challenge (as required by the study protocol), using appropriate autologous target cells infected with recombinant virus or pulsed with peptide. Appropriate control targets, pulsed with a non-specific antigen or vector must be included in the assays.

        4) Characterize SIV or HIV antigen-specific CTL activity that is detected. Studies to be conducted at the request of the Project Officer may include: (1) the determination that the CTL effector cells are CD8+ cells rather than CD4+ cells, (2) the exclusion of NK (natural killer) and ADCC (antibody-dependent complement-mediated cytotoxicity) activity, (3) the determination that the CTL activity is MHC restricted, (4) the determination of the CTL precursor frequency by limiting dilution analysis, or other appropriate method, (5) the identification of the epitopes being recognized, and (6) the generation of T cell clones with anti-HIV or anti-SIV cytotoxic activity.

    b. Perform assays, such as ELISPOT and intracellular cytokine assays, that use cytokine secretion or other appropriate endpoints to detect cellular immune responses to SIV or HIV proteins or peptides.

        1) Receive peripheral blood cells or other tissue samples obtained from animals in vaccine studies being conducted by a SVEU site or by other investigators, as requested by the Project Officer.

        2) Perform assays to detect cellular immune responses directed against SIV or HIV epitopes in naïve, immunized, and/or infected nonhuman primates, as required by each individual vaccine study protocol.

        3) Perform studies to establish the sensitivity and reproducibility of the assays, including the determination of the level of background obtained using samples known to be negative.

4) Characterize SIV or HIV antigen-specific cellular responses that are detected. Additional studies to be conducted at the request of the Project Officer may include: (1) the determination of whether responses are due to CD8+ or to CD4+ T lymphocytes, (2) the characterization of the responsive cells by identificaton of additional cell surface markers, and (3) the mapping of the epitopes being recognized.

c. Perform "tetramer" assays, using primate MHC (major histocompatibility complex)-peptide tetramer complexes to bind to and allow cytoflurometric detection of viral antigen-specific T lymphocytes in immunized and/or infected monkeys.

1) Receive/obtain peripheral blood cells or other tissue samples from animals in vaccine studies conducted by SVEU sites or by other investigators, as requested by the Project Officer.

2) Perform the assays to detect cellular immune responses directed against SIV or HIV epitopes in naïve, immunized, and/or infected nonhuman primates, as specified by the study protocol.

3) Perform studies to determine the sensitivity and reproducibility of the assays, including the determination of the level of background obtained with samples known to be negative.

4) Characterize SIV or HIV antigen-specific cellular responses that are detected. Additional studies to be conducted at the request of the Project Officer may include: (1) the determination of whether responses are due to CD8+ or to CD4+ T lymphocytes and (2) the characterization of the cells by identification of additional cell surface markers.

d. Perform assays to determine the level of viral-specific lymphocyte proliferation in immunized and/or infected animals.

1) Receive peripheral blood cells or other tissue samples obtained from animals in vaccine studies being conducted by a SVEU site or by other investigators, as requested by the Project Officer.

2) Perform assays to detect proliferative cellular immune responses directed against SIV or HIV epitopes in naïve, immunized, and infected nonhuman primates, as required by the study protocol.

3) Perform studies to determine the sensitivity and reproducibility of the assays, including the determination of the level of background obtained with samples known to be negative.

4) Characterize SIV or HIV antigen-specific cellular responses that are detected. Additional studies to be conducted at the request of the Project Officer may include: (1) determination of whether responses are due to CD8+ or to CD4+ T lymphocytes and (2) mapping of the epitopes being recognized.

e. Perform *in vitro* assays to evaluate the ability of CD8+ T lymphocytes (or beta-chemokines released by CD8+ T cells) from immunized and/or infected nonhuman primates to reduce or inhibit HIV, SIV, or SHIV virus replication in either autologous CD4 lymphocytes from the animals in the vaccine studies, or appropriate heterologous target lymphocytes. Include appropriate controls in these assays.

2. Perform assays to evaluate and characterize immune responses at mucosal sites in nonhuman primates immunized with HIV or SIV vaccines or infected with HIV, SHIV, or SIV.

a. Conduct assays to evaluate cellular immune responses (such as CTLs, MHC-peptide tetramer-positive cells, cytokine-secreting cells as described in section I above) in mucosal tissues of immunized and/or infected macaques.

b. Develop an assay or assays that can be used to detect viral-specific cellular responses in mucosal tissue biopsies.

3. For each type of assay conducted under this contract:

a. Demonstrate the level of sensitivity and reproducibility of the selected assay, including the level of signal obtained with virus-negative samples from uninfected animals.

b. Include appropriate positive and negative controls with each set of samples assayed to provide quality control and to ensure the consistency of results of the assay.

c. Conduct comparisons of the selected assay with assays conducted by other commercial or SVEU laboratories as requested by the Project Officer.

d. Provide standardized reagents, methods, and training to outside laboratories as requested by the Project Officer. Serve as a reference laboratory for the conduct of the assay, as requested by the Project Officer, with the objective of evaluating the comparability of the assay among laboratories using the assay in nonhuman primate vaccine studies. On an annual basis, or as requested by the Project Officer, coordinate comparative evaluations of samples with any SVEU laboratory conducting the assay.

4. Develop new or more sensitive assays to detect and evaluate cellular immune responses in immunized and/or infected animals, including assays to detect mucosal immune responses, in order to maintain the capability of providing state-of-the-art assays under this contract. Improve current assays as needed to meet the scope of work.

5. Receive, catalog, track, and maintain an inventory of the specimens that arrive for evaluation:

a. Provide detailed shipping instructions to SVEUs and other sources of specimens, describing the most suitable manner to ship whole blood, cells, or other specimens for evaluation, and arrange for the transfer of the specimens from primate laboratories to the Contractor. Coordinate the timing and other details of shipments to ensure that frozen samples arrive still frozen and that whole blood arrives within 24 hours of shipment. (Overnight shipment or shorter.)

b. Pick up or arrange for pick up of incoming specimen shipments from a specified airport with an hour of arrival or arrange pick up of specimens from other contact sites within one to two hours of sample collection from the animals. Assure maintenance of activity and/or viability of the specimens by providing the appropriate temperature in transit from the airport or other contact site to the Contractor's laboratory.

c. Receive and catalog specimens arriving for evaluation from the primate laboratories. Maintain documentation on file for all incoming specimens, including but not limited to: primate subject identification number, trial site, protocol identification number, specimen collection date and condition of sample upon arrival.

d. Store cataloged, aliquotted specimens under conditions that would be expected to retain maximum immunological and biological activity.

e. Maintain a computer-based specimen tracking and inventory system that allows specimens to be tracked from receipt through processing and assay analysis.

6. Manage and report data:

a. Compile and maintain a computerized file of all assay results. Record results, type of assay, study protocol number, animal number, specimen collection date, and other information specified by the Project Officer. The final format of the file structure will be required to be compatible with a primate vaccine study database being developed by the Government.

b. Report data and results to NIAID and/or to a designated NIAID database contractor: In addition to the required periodic written reports describing the results of assays, additional printouts, electronic transfer of data and verbal reports of the status of assays for a study are to be provided on an ongoing basis during the course of the study, at the request of the Project Officer. Data shall be reported in a format approved by the Project Officer. Data will be transferred electronically to a NIAID Primate Vaccine Database on at least a monthly basis, using a format designated by the Project Officer.

c. Meet with Project Officer and attend Scientific Meetings. Attend meetings (up to two per year) with the Project Officer and other staff of the Preclinical Research and Development Branch, VPRP, DAIDS, NIAID.

d. Obtain clearance for publication and presentations, as outlined in an Advance Understanding.

7. Provide personnel, facilities, and resources necessary to conduct the elements of the Statement of Work:

    a. Provide scientific and technical personnel with the training and experience necessary to meet all requirements of the Statement of Work.

    b. Provide facilities and equipment for the work to be conducted, including at least a biosafety level 2 laboratory equipped to conduct work with live HIV, SIV, and SHIV, as well as samples from infected monkeys.

    c. Provide, maintain, and operate facilities for controlled storage of virus stocks, cell stocks, and other samples and reagents, including storage at -10 to -20 degrees C, at -70 to -90 degrees C, and in liquid nitrogen, with appropriate monitoring of storage conditions to guarantee continuous proper storage. Ensure the reliability of supply systems, electrical power, and backup support systems.

    d. Provide protective garments, equipment and sufficient monitoring to assure safe handling of potentially hazardous materials, including radioactive materials. Specifically, the contractor shall comply with all applicable international, federal, state, and local health and safety regulations while conducting the work set forth herein.

8. Ensure an orderly transition to a successor Contractor:

    By the end of the sixth year of this contract, the Contractor shall refine and implement a plan for an orderly transition of data and specimens to a successor Contractor or to the Government, subject to Project Officer approval, and shall deliver, if requested by the Project Officer and by the completion date of the Contract, the following items: original data, reagents, stored specimens, and any pertinent information, as well as Government owned equipment and property. The Project Officer reserves the right to direct the transfer of equipment from the predecessor contract to this award, and also transfer and equipment purchased under this contract at its conclusion to a to-be-determined location.

[END OF STATEMENT OF WORK – PART A]

STATEMENT OF WORK:
PART B: HUMORAL IMMUNOLOGY LABORATORY

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to provide a Primate Immunology Laboratory that shall support the evaluation of prototype AIDS vaccines in primates in studies conducted at several institutions under the sponsorship of the Division of AIDS, NIAID, NIH, with emphasis on studies conducted at Simian Vaccine Evaluation Unit (SVEU contract sites.

Specifically, the Contractor shall:

1. Perform assays to evaluate and characterize the humoral immune responses of animals immunized with HIV or SIV vaccines and/or infected with HIV, SHIV, or SIV. Assays to be conducted include, but are not limited to, the following:

    a. For animals that have been immunized with HIV vaccines and/or infected with SHIV or HIV:

        1) Perform ELISA, western blot or other appropriate assays to detect the presence of HIV or SIV antibodies in sera or mucosal secretions of immunized and/or infected animals.

        2) Perform assays to determine the ability of sera (or mucosal secretions) from animals immunized with HIV vaccines, or of sera from infected nonhuman primates after SHIV challenge, to neutralize infection of cell lines and/or primary cells (PBMC) by the HIV strain used for the vaccine. Determine the ability of the sera to neutralize the SHIV made with the envelope gene of the homologous (vaccine) HIV, if the appropriate SHIV virus stock is available. Characterize the antibodies, including determining the neutralization titer against the vaccine (homologous) HIV or SHIV strain.

        3) Determine the neutralization titer against infection of appropriate cell lines and/or PBMC by heterologous laboratory strains of HIV or heterologous SHIVs for sera (or mucosal secretions) that were determined (above) to neutralize the homologous strain of HIV or the SHIV containing the envelope gene of the homologous HIV.

        4) Determine the ability to neutralize infection of appropriate cell lines and/or primary PBMC and/or primary macrophages by primary, "field" isolates of HIV grown only in primary cells for sera (or mucosal secretions) that show the ability to neutralize homologous HIV isolates.

    b. For animals that have been immunized with SIV vaccines and/or infected with SIV:

        1) Perform ELISA, western blot or other appropriate assays to detect the presence of SIV antibodies in sera or mucosal secretions of immunized and/or infected animals.

        2) Determine the capability of sera (or mucosal secretions) from animals immunized with SIV vaccines, or infected with SIV, to neutralize infection of cell lines and/or primary cells (PBMC) by the SIV strain used for the vaccine. Further characterize these antibodies, including determining the neutralization titer against the vaccine (homologous) SIV strain.

        3) Determine the neutralization titer against infection of appropriate cell lines and/or PBMC by a heterologous strain or strains of SIV for sera (or mucosal secretions) that were determined (above) to neutralize the homologous strain of SIV.

2. Grow appropriate HIV, SHIV, and SIV virus stocks, determine the *in vitro* titer of the stocks, and demonstrate that the viruses can be neutralized by sera from HIV-infected people or SHIV- or SIV-infected monkeys prior to conducting neutralization assays with the sera from the vaccine studies. The selection of virus stocks to be prepared shall be approved by the Project Officer.

3. Perform assays to evaluate and characterize immune responses at mucosal sites in nonhuman primates immunized with HIV or SIV vaccines and/or infected with HIV, SHIV, or SIV.

    a. Perform assays to detect and measure HIV-specific or SIV-specific antibodies (IgG, IgA, and secretory IgA antibodies) or antibody-secreting cells in mucosal secretions such as vaginal and rectal swabs/washes and saliva of immunized and/or infected macaques. Include assays on appropriate negative control samples.

    b. Develop and conduct assays to evaluate functional humoral immune responses (such as virus neutralization assays as described above) in mucosal secretions or mucosal tissues from immunized and/or infected macaques.

4. For each type of assay conducted under this contract:

    a. Demonstrate the level of sensitivity and reproducibility of the selected assay, including the level of signal obtained with virus-negative samples from uninfected animals.

    b. Include appropriate positive and negative controls with each set of samples assayed to provide quality control and ensure consistency of results of the assay.

    c. Conduct comparisons of the assay with assays conducted by other commercial or SVEU laboratories as requested by the Project Officer.

    d. Provide standardized reagents, methods, and training to outside laboratories as requested by the Project Officer. Serve as a reference laboratory for the conduct of the assay, as requested by the Project Officer, with the objective of evaluating the comparability of the assay among laboratories using the assay in nonhuman primate vaccine studies.

5. Develop new or more sensitive assays to detect and evaluate humoral immune responses in immunized and/or infected animals, in order to maintain the capability of providing state-of- the-art assays under this contract. Improve current assays as needed to meet the scope of work.

6. Receive, catalog, track, and maintain an inventory of the specimens that arrive for evaluation:

    a. Provide detailed shipping instructions to SVEUs and other sources of specimens, describing the most suitable manner to ship sera or other specimens for evaluation, and arrange for the transfer of the specimens from the SVEUs or other primate laboratories to the Contractor. Coordinate the timing and other details of shipments to ensure that frozen samples arrive still frozen.

    b. Pick up or arrange for pick up of incoming specimen shipments from a specified airport within 1-3 hours of arrival and assure maintenance of activity and/or viability of the specimens by providing the appropriate temperature in transit from the airport to the Contractor's laboratory.

    c. Receive and catalog specimens arriving for evaluation from the primate laboratories. Maintain documentation on file for all incoming specimens, including but not limited to: primate subject identification number, trial site, protocol identification number, specimen collection date and condition of sample upon arrival.

    d. Store cataloged, aliquotted specimens under conditions that would be expected to retain maximum immunological and biological activity.

    e. Maintain a computer-based specimen tracking and inventory system that allows specimens to be tracked from receipt through processing and assay analysis.

7. Manage and report data:

    a. Compile and maintain a computerized file of all assay results. Record results, type of assay, study protocol number, animal number, specimen collection date, and other information specified by the Project Officer. The final format of the file structure will be required to be compatible with a primate vaccine study database being developed by the Government.

b. Report data and results to NIAID and/or to a designated NIAID database contractor: In addition to the required periodic written reports describing the results of assays, additional printouts, electronic transfer of data and verbal reports of the status of assays for a study are to be provided on an ongoing basis during the course of the study, at the request of the Project Officer. Data shall be reported in a format approved by the Project Officer. Data will be transferred electronically to a NIAID Primate Vaccine Database on at least a monthly basis, using a format designated by the Project Officer.

c. Meet with Project Officer and attend Scientific Meetings. Attend meetings (up to two per year) with the Project Officer and other staff of the Preclinical Research and Development Branch, VPRP, DAIDS, NIAID.

d. Obtain clearance for publication and presentations, as outlined in an Advance Understanding.

8. Provide personnel, facilities and resources necessary to conduct the elements of the Statement of Work:

a. Provide scientific and technical personnel with the training and experience necessary to meet all requirements of the Statement of Work.

b. Provide facilities and equipment for the work to be conducted, including at least a biosafety level 2 laboratory equipped to conduct work with live HIV, SIV, and SHIV, as well as samples from infected monkeys.

c. Provide, maintain, and operate facilities for controlled storage of virus stocks, cell stocks, and other samples and reagents, including storage at -10 to -20 degrees C, at -70 to -90 degrees C, and in liquid nitrogen, with appropriate monitoring of storage conditions to guarantee continuous proper storage. Ensure the reliability of supply systems, electrical power, and backup support systems.

d. Provide protective garments, equipment and sufficient monitoring to assure safe handling of potentially hazardous materials, including radioactive materials. Specifically, the contractor shall comply with all applicable international, federal, state, and local health and safety regulations while conducting the work set forth herein.

9. Ensure an orderly transition to a successor Contractor:

By the end of the sixth year of this contract, the Contractor shall refine and implement a plan for an orderly transition of data and specimens to a successor Contractor or to the Government, subject to Project Officer approval, and shall deliver, if requested by the Project Officer and by the completion date of the Contract, the following items: original data, reagents, stored specimens, and any pertinent information, as well as Government owned equipment and property. The Project Officer reserves the right to direct the transfer of equipment from the predecessor contract to this award, and also transfer and equipment purchased under this contract at its conclusion to a to-be-determined location.

[END OF STATEMENT OF WORK – PART B]

STATEMENT OF WORK:
PART C: QUANTITATIVE VIRAL RNA LABORATORY

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to provide a Primate Virology Laboratory that shall support the evaluation of prototype AIDS vaccines in primates in studies conducted at several institutions under the sponsorship of the Division of AIDS, NIAID, NIH, with emphasis on studies conducted at Simian Vaccine Evaluation Unit (SVEU) contract sites.

Specifically, the Contractor shall:

1. Perform assays to quantitatively determine the level of SIV or SHIV viral RNA in plasma of nonhuman primates infected with SIV or SHIV. Assays to be conducted may include, but are not to be limited to, bDNA, NASBA, or PCR assays. The assay should be capable of detecting the RNA of a variety of SHIV and SIV viruses.

    a. Demonstrate the level of sensitivity and reproducibility of the selected assay, including the level of signal obtained with virus-negative samples from uninfected animals.

    b. Include appropriate positive and negative controls with each set of samples assayed to provide quality control and ensure consistency of results of the assay.

    c. Conduct assays to detect levels of viral RNA below the level of detection of the standard assay being used, even though such assays may not be quantitative.

    d. Conduct comparisons of the selected assay with assays conducted by other commercial or SVEU laboratories as requested by the Project Officer.

    e. Provide standardized reagents, methods, and training to outside laboratories as requested by the Project Officer. Serve as a reference laboratory for the conduct of the assay, as requested by the Project Officer, with the objective of evaluating the comparability of the assay among laboratories using the assay in nonhuman primate vaccine studies. On an annual basis, or as requested by the Project Officer, coordinate comparative evaluations of samples with any SVEU laboratory conducting the assay.

2. Perform assays as above to detect and characterize viral RNA in mucosal tissues or secretions, lymphoid tissue, or other tissue from nonhuman primates infected with HIV, SHIV, or SIV.

3. Develop new or more sensitive assays to quantitatively detect viral nucleic acids in infected animals, in order to maintain the capability of providing state-of- the-art assays under this contract. Improve current assays as needed to meet the scope of work.

4. Receive, catalog, track, and maintain an inventory of the specimens that arrive for evaluation:

    a. Provide detailed shipping instructions to SVEUs and other sources of specimens, describing the most suitable manner to ship plasma or other specimens for evaluation, and arrange for the transfer of the specimens from the SVEUs or other primate laboratories to the Contractor. Coordinate the timing and other details of shipments to ensure that frozen samples arrive still frozen.

    b. Pick up or arrange for pick up of incoming specimen shipments from a specified airport within 1-3 hours of arrival and assure maintenance of activity and/or viability of the specimens by providing the appropriate temperature in transit from the airport to the Contractor's laboratory.

    c. Receive and catalog specimens arriving for evaluation from the primate laboratories. Maintain documentation on file for all incoming specimens, including but not limited to: primate subject identification number, trial site, protocol identification number, specimen collection date and condition of sample upon arrival.

    d. Store cataloged specimens under appropriate conditions that would be expected to retain maximum immunological and biological activity.

e. Maintain a computer-based specimen tracking and inventory system that allows specimens to be tracked from receipt through processing and assay analysis.

5. Manage and report data:

   a. Compile and maintain a computerized file of all assay results. Record results, type of assay, study protocol number, animal number, specimen collection date, and other information specified by the Project Officer. The final format of the file structure will be required to be compatible with a primate vaccine study database being developed by the Government.

   b. Report data and results to NIAID and/or to a designated NIAID database contractor: In addition to the required periodic written reports describing the results of assays, additional printouts, electronic transfer of data and verbal reports of the status of assays for a study are to be provided on an ongoing basis during the course of the study, at the request of the Project Officer. Data shall be reported in a format approved by the Project Officer. Data will be transferred electronically to a NIAID Primate Vaccine Database on at least a monthly basis, using a format designated by the Project Officer.

   c. Meet with Project Officer and attend Scientific Meetings. Attend meetings (up to two per year) with the Project Officer and other staff of the Preclinical Research and Development Branch, VPRP, DAIDS, NIAID.

   d. Obtain clearance for publication and presentations, as outlined in an Advance Understanding.

6. Provide personnel, facilities and resources necessary to conduct the elements of the Statement of Work:

   a. Provide scientific and technical personnel with the training and experience necessary to meet all requirements of the Statement of Work.

   b. Provide facilities and equipment for the work to be conducted, including at least a biosafety level 2 laboratory equipped to conduct work with live HIV, SIV, and SHIV, as well as samples from infected monkeys.

   c. Provide, maintain, and operate facilities for controlled storage of virus stocks, cell stocks, and other samples and reagents, including storage at -10 to -20 degrees C, at -70 to -90 degrees C, and in liquid nitrogen, with appropriate monitoring of storage conditions to guarantee continuous proper storage. Ensure the reliability of supply systems, electrical power, and backup support systems.

   d. Provide protective garments, equipment and sufficient monitoring to assure safe handling of potentially hazardous materials, including radioactive materials. Specifically, the contractor shall comply with all applicable international, federal, state, and local health and safety regulations while conducting the work set forth herein.

7. Ensure an orderly transition to a successor Contractor:

   By the end of the sixth year of this contract, the Contractor shall refine and implement a plan for an orderly transition of data and specimens to a successor Contractor or to the Government, subject to Project Officer approval, and shall deliver, if requested by the Project Officer and by the completion date of the Contract, the following items: original data, reagents, stored specimens, and any pertinent information, as well as Government owned equipment and property. The Project Officer reserves the right to direct the transfer of equipment from the predecessor contract to this award, and also transfer and equipment purchased under this contract at its conclusion to a to-be-determined location.

[END OF STATEMENT OF WORK – PART C]

Notes To Offerors
Primate Core Immunology-Virology Laboratories
RFP-DAIDS-03-02

GENERAL NOTE #1 TO OFFERORS: Because of the wide diversity of services required by this RFP, Offerors have the option of submitting proposals to conduct the work for one, two, or all three parts of the Statement of Work. The number of parts of the SOW proposed will not be a factor in reviewing and scoring the proposals. However, the proposals for each, PART A, B, or C, even if all three are proposed by one Offeror, must be separate and complete. Each must contain all the information needed to stand alone (i.e., separate personnel and technical approach information, separate support documents, bibliographies, appendices, business proposal, etc.). Each part will be scored separately and may be awarded separately.

Offerors may submit proposals for:

PART A: Cellular Immunology Laboratory,
PART B: Humoral Immunology Laboratory, or
PART C: Quantitative RNA Laboratory as individual proposals.

EXAMPLE: PARTS A + B
PARTS A + C
PARTS B + C
PARTS A + B + C

Negotiations will take place with Offerors whose proposals are determined to be in the competitive range. If Part A, Part B, and Part C from a single Offeror are in the competitive range, the government reserves the right to negotiate a single contract and the Offeror's Statement of Work will comprise all of the relevant Parts of the award.

NOTES FOR PART A

[Section 1.a.] NOTE #2 TO OFFERORS: For purposes of preparing a cost proposal, Offerors should propose to conduct CTL assays on 1000 samples per year (on PBMCs from 100 monkeys, 10 assays per monkey). Offerors should assume that they will mainly conduct assays to detect HIV and SIV env-specific and gag-specific CTLs, but that they will be requested, less frequently, to conduct assays to detect CTLs directed at other viral targets, such as pol and nef.

[Section 1.a.1)] NOTE #3 TO OFFERORS: For purposes of preparing a cost proposal, Offerors should propose to establish and maintain transformed B cell lines for 100 monkeys each year.

[Section 1.a.4)] NOTE #4TO OFFERORS: For purposes of preparing a cost proposal, Offerors should assume that 10% of the samples will require further characterization.

[Section 1.b.] NOTE #5 TO OFFERORS: For purposes of preparing a cost proposal, Offerors should assume that they will be requested to perform peptide-stimulated cytokine ELISPOT assays on 20,000 nonhuman primate samples per year.

[Section 1.b.] NOTE #6 TO OFFERORS: For purposes of preparing a cost proposal, Offerors should assume that they will be requested to perform intracellular cytokine assays on 2000 nonhuman primate samples per year.

[Section 1.b.] NOTE #7 TO OFFERORS: For purposes of preparing a cost proposal, Offerors should include the cost of ordering peptides for the ELISPOT and intracellular cytokine assays. Assume that a minimum of 10 mg each of peptides covering two envelope glycoproteins, one p55 Gag, and one each of Tat, Nef, Rev, and Vif will be required per year.

[Section 1.c.] NOTE #8 TO OFFERORS: For purposes of preparing a cost proposal, Offerors should assume that they will be requested to perform tetramer staining assays on 1200 nonhuman primate samples per year.

[Section 1.d.] NOTE #9 TO OFFERORS: For purposes of preparing a cost proposal, Offerors should assume that they will be requested to perform proliferation assays on 500 nonhuman primate samples per year.

[Section 4.] NOTE #10 TO OFFERORS: For purposes of preparing a cost proposal, Offerors are requested to discuss their experience in improving existing and developing new immunological assays, and may propose budgetary commitments of personnel and materials to this aspect of the Statement of Work, but no additional budgetary provisions are required.

[Section 6.c.] NOTE #11 TO OFFERORS: For purposes of preparing a cost proposal, Offerors should assume two trips a year for the Principal Investigator (or designate) and the Co-investigator (or designate) to attend meetings with the Project Officer in the Washington, D.C. metropolitan area (although meetings with the Project Officer may be held in Bethesda/Rockville, at contract Site Visits, or at other locations designated by the Project Officer). For purposes of preparing a cost proposal, Offererrs should assume that the Principal Investigator and the Co-Investigator may each attend one domestic Scientific Meeting a year to present results obtained by this contract, with the approval of the Project Officer.

[Section 6.d.] NOTE #12 TO OFFERORS: For purposes of protecting proprietary rights of vaccine providers, an Advance Understanding will be inserted in any resultant contract, stating that the Contractor agrees to provide to the Project Officer advance copies of manuscripts and abstracts resulting from data generated under this contract and to obtain clearance from the Project Officer for publication or presentation. In addition, the Contractor shall be bound to maintain confidentiality of information provided by vaccine product providers. Data from assays conducted under this contract shall be published or presented only in the context of the vaccine study for which the work was conducted. Support provided by the Government contract must be acknowledged in all abstracts, presentations, and publications.

NOTES FOR PART B

[Sections 1.a.3) and 1.b.2.)] NOTE #13 TO OFFERORS: For purposes of preparing a cost proposal, Offerors should propose to conduct virus neutralization assays on 7,000 serum samples per year using cell line-based assays, with SIV, SHIV, or HIV-1 viruses.

[Sections 1.a.4) and 1.b.3)] NOTE #14 TO OFFERORS: For purposes of preparing a cost proposal, Offerors should propose to conduct virus neutralization assays on 4,000 serum samples per year in PBMC-based assays using primary isolates of HIV-1.

[Section 2.] NOTE #15 TO OFFERORS: The SHIV, HIV or SIV strain to be used in the neutralization assays will be determined by the strain used in the vaccine and the strain(s) selected for heterologous challenge. For purposes of preparing a cost proposal, Offerors should assume that stocks of four cell-line-adapted strains of HIV-1, stocks of twenty five primary HIV-1 isolates, stocks of four SHIVs, and stocks of three SIVs will be made and titered for the *in vitro* neutralization assays.

[Section 5.] NOTE #16 TO OFFERORS: For purposes of preparing a cost proposal, Offerors are requested to discuss their experience in improving existing and developing new immunological assays, and may propose budgetary commitments of personnel and materials to this aspect of the Statement of Work, but no additional budgetary provisions are required.

[Section 7.c.] NOTE #17 TO OFFERORS: For purposes of preparing a cost proposal, Offerors should assume two trips a year for the Principal Investigator (or designate) and the Co-investigator (or designate) to attend meetings with the Project Officer in the Washington, D.C. metropolitan area (although meetings with the Project Officer may be held in Bethesda/Rockville, at contract Site Visits, or at other locations designated by the Project Officer). For purposes of preparing a cost proposal, Offererrs should assume that the Principal Investigator and the Co-Investigator may each attend one domestic Scientific Meeting a year to present results obtained by this contract, with the approval of the Project Officer.

[Section 7.d.] NOTE #18 TO OFFERORS: For purposes of protecting proprietary rights of vaccine providers, an Advance Understanding will be inserted in any resultant contract, stating that the Contractor agrees to provide to the Project Officer advance copies of manuscripts and abstracts resulting from data generated under this contract and to obtain clearance from the Project Officer for publication or presentation. In addition, the Contractor shall be bound to maintain confidentiality of information provided by vaccine product providers. Data from assays conducted under this contract shall be published or presented only in the context of the vaccine study for which the work was conducted. Support provided by the Government contract must be acknowledged in all abstracts, presentations, and publications.

NOTES FOR PART C

[Section 1.] NOTE #19 TO OFFERORS: For purposes of preparing a cost proposal, Offerors should propose to conduct assays to quantitatively measure viral RNA in 6000 nonhuman primate plasma samples per year.

[Section 3.] NOTE #20 TO OFFEROR: For purposes of preparing a cost proposal, Offerors are requested to discuss their experience in improving existing and developing new viral RNA assays, and may propose budgetary commitments of personnel and materials to this aspect of the Statement of Work, but no additional budgetary provisions are required.

[Section 5.c.] NOTE #21 TO OFFEROR: For purposes of preparing a cost proposal, Offerors should assume two trips a year for the Principal Investigator (or designate) and the Co-investigator (or designate) to attend meetings with the Project Officer in the Washington, D.C. metropolitan area (although meetings with the Project Officer may be held in Bethesda/Rockville, at contract Site Visits, or at other locations designated by the Project Officer). For purposes of preparing a cost proposal, Offererrs should assume that the Principal Investigator and the Co-Investigator may each attend one domestic Scientific Meeting a year to present results obtained by this contract, with the approval of the Project Officer.

[Section 5.d.] NOTE #22 TO OFFEROR: For purposes of protecting proprietary rights of vaccine providers, an Advance Understanding will be inserted in any resultant contract, stating that the Contractor agrees to provide to the Project Officer advance copies of manuscripts and abstracts resulting from data generated under this contract and to obtain clearance from the Project Officer for publication or presentation. In addition, the Contractor shall be bound to maintain confidentiality of information provided by vaccine product providers. Data from assays conducted under this contract shall be published or presented only in the context of the vaccine study for which the work was conducted. Support provided by the Government contract must be acknowledged in all abstracts, presentations, and publications.

DELIVERABLES AND REPORTING REQUIREMENTS

1. Reporting Requirements

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to technical inspection and requests for clarification by the Project Officer. These shall be brief and factual and prepared in accordance with the following format:

2. Quarterly Progress Reports

By the fifteenth calendar day of the month following the end of each quarter, the Contractor shall submit three (3) copies of a quarterly progress report as described below. Two (2) copies should be submitted to the Project Officer and one (1) copy to the Contracting Officer. A quarterly report is not due when an annual or final reports are due. The quarterly report should be factual and concise and consist of the following:

a. A title page containing:

1) Contract number and title
2) Sequence of report; e.g., "Year 1, 2nd Quarterly Report"
3) Period of performance being reported
4) Contractor's name and address
5) Date of submission

b. Reports shall include, but are not limited to the following information:

1) A brief introduction covering the objective and scope of the contract effort.

2) A description of overall progress

3) Descriptions of the methodology and reagents employed for each immunological assay employed during the performance period, specifying changes in critical reagents or protocols.

4) Separate tables listing:

a) An inventory of specimens received during the performance period, but on which assays have not yet been performed.

b) An inventory of the specimens on which assays were performed during the performance period.

c) An inventory of the assays performed during the performance period, indicating number of each performed.

d) Results of assays conducted on specimens received during the performance period. Results are to be grouped by the SVEU study protocol number or by the independent investigator's name and are to be identified by animal number, date, and any other relevant information provided with the specimen. **When new assays are conducted as part of an ongoing study, include the results from previous reports so that a complete and updated data set for ongoing studies is included in each report. Graphical representation of the data is to be provided whenever possible.**

5) A description of any technical or performance problems encountered and corrective actions planned or taken. An explanation of any differences between planned and actual progress should be included.

6) Selected other information as required by the Project Officer.

3. Annual Report

The Contractor shall submit three (3) copies of an annual report on the 30th of the month following each anniversary date of the contract. Two (2) copies shall be submitted to the Project Officer and one (1) copy shall be submitted to the Contracting Officer. The annual report shall summarize progress for the entire contract year, following the same format as for the quarterly reports, and shall take the place of the fourth quarterly report. In addition, it should include abstracts, manuscripts in progress or submitted, and publications resulting from the performance of work under this contract. An annual report is not required when the final report is due.

4. Final Report

The contractor shall submit three (3) copies of the final report documents, two (2) copies to the Project Officer and one (1) copy to the Contracting Officer, which will summarize the results of the entire contract work for the complete performance period. This report will be in sufficient detail to explain comprehensively the results achieved and will be submitted on or before the completion date of the Contract.

With the Final Report, the Contractor shall submit a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

The final report will contain:

a. Title Page as described above in paragraph I.1.a.

b. Introduction covering the purpose and scope of the contract effort.

c. Description of the overall progress, plus a separate description of each protocol and type of assay employed and its modifications and performance on the contract during the period of performance. Descriptions will include pertinent immunological assay data in tables or graphs as appropriate to present significant results achieved, conclusions resulting from analysis, and a scientific evaluation of the data accrued under the contract.

d. Copies of any abstracts, manuscripts, and publications.

5. Electronic Reports of Data

The Contractor shall electronically deliver assay result data to an NIAID-sponsored Primate Vaccine Study database. Data from studies conducted at NIAID's Simian Vaccine Evaluation Unit contract sites, as well as data from other studies designated by the Project Officer, shall be sent to the database using the format designated by the Project Officer.

6. Other Deliverables

The Contractor, at the request of the Project Officer, shall deliver to the Government or its designee the following items:

a. An up-to-date protocol or Standard Operating Procedure for each type of assay conducted in performance of this contract, to be included in each quarterly report.

b. Stored primate-derived specimens or reagents received by the Contractor from the Project Officer or designated investigators.

c. An accurate and up-to-date computer-generated specimen inventory, contract-related computerized data files, contract-related original data, and any additional contract-related information.

d. Labeled and inventoried contract-related paper files.

If the Contractor becomes unable to deliver the reports or other deliverables here specified within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons therefore at the address given below in section VII.

6. Copies of the technical reports shall be submitted as follows:

Type of Report	No. of Copies	Due Date
Quarterly Technical Report	2 – Project Officer 1 – Contracting Officer	Due the 15th calendar day of the month following each 3-month period. Not due when Annual and Final Reports are due.
Annual Technical Report	2 – Project Officer 1 – Contracting Officer	Due the 30th of the month following each anniversary date of the contract. Not due when Final Report is due.
Final Report	2 – Project Officer 1 – Contracting Officer	Due on/before the completion date of the contract.
Summary of Salient Results	2 – Project Officer 1 – Contracting Officer	Due with the Final Report.
Electronic Reports of Data	To be determined	To be determined.
Other Deliverables	To be determined	As designated by Project Officer

Addressees:

Project Officer
Vaccine and Prevention Research Program (VPRP)
Preclinical Research and Development Branch (PRDB)
DAIDS, NIAID, NIH
6700B Rockledge Drive, Room ____, MSC 7628
Bethesda, MD 20892-7628

Contracting Officer
Contract Management Branch, DEA, NIAID, NIH
6700B Rockledge Drive, Room 2230, MSC 7612
Bethesda, MD 20892-7612

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm

[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

BECAUSE THIS IS A STREAMLINED RFP, ARTICLES I.2. AND I.3., WHICH IDENTIFY ANY AUTHORIZED ADDITIONS, SUBSTITUTIONS AND/OR MODIFICATIONS TO THE GENERAL CLAUSES, WILL BE BASED ON THE TYPE OF CONTRACT/CONTRACTOR AND WILL BE DETERMINED DURING NEGOTIATIONS.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this URL: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

FAR Clause No.	Date	Title
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Feb 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)

52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs

52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR Clause No.	Date	Title
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – Rev. 05/2002]

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: September 30, 2002] (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

http://www.niaid.nih.gov/contract/ref.htm

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **Technical Proposal Cover Sheet**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Government Notice for Handling Proposals**

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- **NIH-2043, Proposal Summary and Data Record**
- **Small Business Subcontracting Plan Format *[if applicable]***
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contact**

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Report of Government Owned, Contractor Held Property**
- **Government Property – Schedule ___**
- **Disclosure of Lobbying Activities, OMB Form LLL**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals. *You are required to submit one original paper copy of your proposal along with the number of extra copies required below.*

ELECTRONIC SUBMISSION: *In addition to the paper submission, you are required to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical.*

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

Shipment and marking of paper copies shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DAIDS-03-02
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES and CD-Rom or ZipDisk to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Lois Eaton Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Lois Eaton Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 75 PAGES
[INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF "PROPOSAL INTENT TO RESPOND SHEET":

Upon receipt by the Contracting Officer of the "Proposal Intent Response Sheet", offerors will be provided, via e-mail correspondence, specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached "Proposal Intent Response Sheet" by the date provided on that Attachment.

CREATE ADOBE PDF ONLINE -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs $10/month or $100/year. Please link to the following URL for information:

https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE

LOG-IN / TRANSMISSION INSTRUCTIONS:

1. Log-in Site: Will be provided by the Contract Specialist after receipt of the "Proposal Intent Response Sheet"
2. Log-in Name: Will be provided by the Contract Specialist.
3. Log-in Password: Will be provided by the Contract Specialist.

4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.

- You must have Explorer 3.1 or higher.
- It is essential that you use antiviral software to scan all documents.
- Click on "Sign On" and enter your log-in name and password.
- Click on "Browse" to locate your saved files on your computer.
- Click on "Upload Proposal" after you have located the correct file.
- After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
- If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
- If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-03-02
RFP Title: Primate Core Immunology - Virology Laboratories

Please review the attached Request for Proposal. Furnish the information requested below and return this page by September 30, 2002. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Lois Eaton
RFP-NIH-NIAID-DAIDS-03-02
FAX# (301) 402-0972
Email: le52u@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*", "writing", or "*written*" any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it

is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

b. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.
(2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS**

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10% percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

d. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that three (3) to four (4) awards will be made from this solicitation and that the awards will be made on/about June 30, 2003.

It is anticipated that the awards from this solicitation will be multiple-year COST REIMBURSEMENT, COMPLETION type contracts with a PERIOD OF PERFORMANCE OF seven (7) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **ESTIMATE OF EFFORT**

To assist you in the preparation of your proposal, the Government considers the effort to be approximately as follows:

PART A - 24,336 labor hours per year (11.70 FTEs/year)
PART B - 15,600 labor hours per year (7.50 FTEs/year)
PART C - 2,496 labor hours per year (1.20 FTEs/year)

This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

j. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

k. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

l. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

m. **USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS**

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

2. INSTRUCTIONS TO OFFERORS

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Care of Live Vertebrate Animals**

a. The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

b. If an Animal Assurance is already in place, the offeror's proposal shall include:

-The Animal Welfare Assurance number.
-The date last certified by OLAW. (i.e. assurance letter from OLAW)
-Evidence of recent AAALAC Accreditation.

(10) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website:
http://ott.od.nih.gov/NewPages/64FR72090.pdf.

(11) **Privacy Act (Treatment of Proposal Information)**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(12) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding $25,000 will be published in the FedBizOpps.

(13) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment _ to this RFP is an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

(1) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(2) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

The Department of Commerce website for the annual determination is:
http://www.arnet.gov/References/sdbadjustments.htm

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

***NOTE:** FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(3) **Reimbursement of Costs for Independent Research and Development Projects** (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(4) **Salary Rate Limitation in Fiscal Year 2003** **

Offerors are advised that pursuant to P.L. 107-116, no NIH Fiscal Year 2002 (October 1, 2001 - September 30, 2002) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 107-116 applies only to Fiscal Year 2002 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 107-116 states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

Information regarding the FY-2002 rate can be found at: http://www.opm.gov/oca/02tables/ex.pdf

It should be noted that a similar public law may be enacted in Fiscal Year 2003, at which time that public law will be incorporated into any resultant contract(s).

(5) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(6) **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(7) **Electronic and Information Technology Accessibility**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

1. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

2. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

(8) **Solicitation Provisions Incorporated by Reference**, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

b) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

c) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

c. **BUSINESS PROPOSAL INSTRUCTIONS**

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) Information Other than Cost or Pricing Data

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

   Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

   Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

   Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

   Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

   If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

    List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

    To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: http://rcb.nci.nih.gov/forms/cpi.htm

(4) Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

(5) Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(6) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

e) **Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)**

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(7) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(8) Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(9) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(10) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

GENERAL

The major evaluation factors for this solicitation include technical (which encompasses experience and past performance factors) cost/price factors and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation is also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based upon the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

The technical proposals will receive paramount consideration in the selection of the Contractor for this acquisition. The evaluation will be based on the demonstrated capabilities of the prospective contractors in relation to the needs of the project as set forth in the RFP. The merit of each proposal will be evaluated carefully, based on responsiveness to the RFP and thoroughness and feasibility of the technical approach taken. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below. Failure to provide the information required to evaluate the proposal may result in rejection of that proposal without further consideration. **If an Offeror has submitted proposals for Parts A, B and C, each will be reviewed and evaluated as a separate, individual proposal.**

For the purposes of review, Parts A, B and C must be able to stand-alone and will be separately reviewed against their respective evaluation criteria. A separate Competitive Range will be established for each Part. If an offeror responds to multiples of Parts A, B and C, only those parts placed in the competitive range will enter the negotiation phase.

1. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Realism of the proposal
(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
(f) Extent of participation of SDB concerns in terms of the value of the total acquisition.

2. **TECHNICAL EVALUATION CRITERIA – PART A**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

PART A:

PROPOSALS SUBMITTED IN RESPONSE TO PART A OF THIS RFP WILL BE EVALUATED BASED ON THE FOLLOWING FACTORS WHICH ARE LISTED AND WEIGHTED IN ORDER OF THEIR RELATIVE IMPORTANCE. PROPOSALS WILL BE JUDGED SOLELY ON THE WRITTEN MATERIAL PROVIDED BY THE OFFEROR.

PART A --- CELLULAR IMMUNOLOGY LABORATORY

CRITERIA	WEIGHT
1. PERSONNEL	**50**

Adequacy and suitability of the documented training, experience, scientific expertise, and availability of the Principal Investigator and other proposed professional and technical staff (including any consultants or subcontractors) necessary to perform the specified tasks, including experience in the conduct of large numbers of the specified assays for multiple collaborations:

Adequacy and suitability of the documented training, experience, scientific expertise, and availability of the Principle Investigator and appropriate scientific staff in conducting assays to detect and characterize HIV-specific or SIV-specific cellular immune responses in peripheral blood of nonhuman primates that have been immunized with HIV or SIV vaccines or infected with SHIV or SIV, to include:

a) assays to detect cytotoxic T cell (CTL) activity directed against SIV or HIV proteins or peptides
b) SIV- or HIV-specific peptide-stimulated ELISPOT assays
c) SIV- or HIV-specific Intracellular Cytokine Assays
d) Nonhuman primate SIV- or HIV-specific Tetramer assays
e) Assays to measure proliferative responses to SIV or HIV peptides or proteins
f) CD8 suppressor cell activity that inhibits SIV, SHIV, or HIV replication in CD4+ lymphocytes

Adequacy and suitability of the documented training, experience, scientific expertise, and availability of the Principle Investigator and appropriate scientific staff in conducting assays to detect and characterize immune responses in mucosal, lymphoid, or other tissues of nonhuman primates immunized with HIV or SIV vaccines or infected with HIV, SHIV, or SIV, with emphasis on experience in conducting the assays on biopsy specimens.

Adequacy and suitability of the documented training, experience, scientific expertise, and availability of the Principle Investigator and appropriate scientific staff in developing assays for the detection of cellular immune responses in nonhuman primates.

Adequacy and suitability of the documented experience of the Principal Investigator in the management, administration, and coordination of a laboratory that has conducted a large number of assays in collaboration with multiple investigators.

Adequacy and suitability of the documented training and experience of appropriate staff in the management of computer data files for the storage and reporting of data from the laboratory.

2. TECHNICAL APPROACH/METHODOLOGY **40**

Adequacy, logic, comprehensiveness, and scientific and technical appropriateness of the proposed technical approaches and methodologies to be used to conduct the tasks specified in the Statement of Work. Completeness of description of the proposed methodologies and thoroughness of discussion of potential problems and appropriate controls and alternate approaches to be used to conduct the proposed tasks:

Detection and characterization of cellular immune responses of nonhuman primates that have been immunized with HIV or SIV vaccines or infected with HIV, SHIV, or SIV, including:

a) assays to detect cytotoxic T cell (CTL) activity directed against SIV or HIV proteins or peptides
b) SIV- or HIV peptide-stimulated ELISPOT assays
c) SIV- or HIV-specific Intracellular Cytokine Assays
d) Nonhuman primate SIV- or HIV-specific Tetramer assays
e) Assays to measure proliferative responses to SIV or HIV peptides or proteins
f) CD8 suppressor cell activity that inhibits SIV, SHIV, or HIV replication in CD4+ lymphocytes

Detection and characterization of cellular immune responses in mucosal, lymphoid, or other tissues of nonhuman primates immunized with HIV or SIV vaccines or infected with HIV, SHIV, or SIV, with emphasis on the detection of viral-specific cellular responses in biopsy samples.

Acquisition, storage, and management of specimens submitted for assays. Tabulation of assay results and maintenance of computer datafiles for assay results. Electronic transfer of data to a centralized NIAID-supported database.

Establishment and maintenance of a Cellular Immunity Reference Laboratory capability.

RESOURCES AND FACILITIES **10**

Adequacy, suitability, and documented availability of laboratory facilities, resources, and equipment necessary to conduct the specified tasks, including appropriate (at least BSL-2) biocontainment laboratory facilities for conducting work with live, infectious SIV, SHIV, or HIV .

Adequacy, suitability, and documented availability of computer resources for data reporting.

Adequacy and suitability of the Offeror's Safety Plan, including personnel training procedures.

Adequacy and suitability of the plan for a transition to a successor contractor at the end of this contract period.

TOTAL: 100

4. **TECHNICAL EVALUATION CRITERIA – PART B**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

PART B:

PROPOSALS SUBMITTED IN RESPONSE TO PART A OF THIS RFP WILL BE EVALUATED BASED ON THE FOLLOWING FACTORS WHICH ARE LISTED AND WEIGHTED IN ORDER OF THEIR RELATIVE IMPORTANCE. PROPOSALS WILL BE JUDGED SOLELY ON THE WRITTEN MATERIAL PROVIDED BY THE OFFEROR.

PART B --- HUMORAL IMMUNOLOGY LABORATORY

CRITERIA	WEIGHT
1. PERSONNEL	**50**

Adequacy and suitability of the documented training, experience, scientific expertise, and availability of the Principal Investigator and other proposed professional and technical staff (including any consultants or subcontractors) necessary to perform the specified tasks, including experience in the conduct of large numbers of the specified assays for multiple collaborations:

Adequacy and suitability of the documented training, experience, scientific expertise, and availability of the Principal Investigator and appropriate scientific staff in developing and conducting assays to detect and characterize the humoral immune responses of animals immunized with HIV or SIV vaccines or infected with HIV, SHIV, or SIV, including:

a) ELISA and western blot assays to detect the presence of HIV- or SIV-specific antibodies
b) Assays to detect and determine the titer of neutralizing antibodies directed against SHIV, HIV, or SIV, using a cell line-based assay
c) Assays to detect and determine the titer of neutralizing antibodies directed against primary isolates of HIV-1, using a primary cell-based assay

Adequacy and suitability of the documented training, experience, scientific expertise, and availability of the Principal Investigator and appropriate scientific staff in developing and conducting assays to detect and characterize immune responses at mucosal surfaces or in mucosal secretions of nonhuman primates immunized with HIV or SIV vaccines or infected with SHIV or SIV, including assays to detect HIV- and SIV-specific IgG and IgA,

Adequacy and suitability of the documented experience of the Principal Investigator in the management, administration, and coordination of a laboratory that has conducted a large number of assays in collaboration with multiple investigators.

Adequacy and suitability of the documented training and experience of appropriate staff in the management of computer data files for storage and retrieval of assay results.

2. TECHNICAL APPROACH/METHODOLOGY **40**

Adequacy, logic, comprehensiveness, and scientific and technical appropriateness of the proposed technical approaches and methodologies to be used to conduct the tasks specified in the Statement of Work. Completeness of description of the proposed methodologies and thoroughness of discussion of potential problems and appropriate controls and alternate approaches to be used to conduct the proposed tasks:

Detection and characterization of humoral immune responses in the serum of animals immunized with HIV or SIV vaccines or infected with HIV, SHIV, or SIV, including:

a) ELISA and western blot assays to detect the presence of HIV- or SIV-specific antibodies
b) Assays to detect and determine the titer of neutralizing antibodies directed against SHIV, HIV, or SIV, using a cell line-based assay
c) Assays to detect and determine the titer of neutralizing antibodies directed against primary isolates of HIV-1, using a primary cell-based assay

Preparation and characterization of HIV, SHIV, and SIV virus stocks for use in neutralization assays.

Detection and characterization of immune responses at mucosal surfaces or in mucosal secretions of nonhuman primates immunized with HIV or SIV vaccines or infected with HIV, SHIV, or SIV, including assays to detect HIV- and SIV-specific IgG, IgA

Acquisition, storage, and management of specimens submitted for assay.

Tabulation of assay results and maintenance of computer data files for assay results. Electronic transfer of data to a centralized NIAID-supported database.

Establishment and maintenance of a Virus Neutralization Reference Laboratory capability.

3. RESOURCES AND FACILITIES **10**

Adequacy, suitability, and documented availability of laboratory facilities, resources, and equipment necessary to conduct the specified tasks, including appropriate (at least BSL-2) biocontainment laboratory facilities for conducting work with live, infectious SIV, SHIV, or HIV.

Adequacy, suitability, and documented availability of computer resources for data reporting.

Adequacy and suitability of the Offeror's Safety Plan, including personnel training procedures.

Adequacy and suitability of the plan for a transition to a successor contractor at the end of this contract period.

TOTAL: 100

3. TECHNICAL EVALUATION CRITERIA – PART C

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

PART C:

PROPOSALS SUBMITTED IN RESPONSE TO PART A OF THIS RFP WILL BE EVALUATED BASED ON THE FOLLOWING FACTORS WHICH ARE LISTED AND WEIGHTED IN ORDER OF THEIR RELATIVE IMPORTANCE. PROPOSALS WILL BE JUDGED SOLELY ON THE WRITTEN MATERIAL PROVIDED BY THE OFFEROR.

PART C: QUANTITATIVE VIRAL RNA LABORATORY

CRITERIA	WEIGHT
1. PERSONNEL	**50**

Adequacy and suitability of the documented training, experience, scientific expertise, and availability of the Principal Investigator and other proposed professional and technical staff (including any consultants or subcontractors) necessary to perform the specified tasks, including experience in the conduct of large numbers of the specified assays for multiple collaborations:

Adequacy and suitability of the documented training, experience, scientific expertise, and availability of the Principle Investigator and appropriate scientific staff in performing assays to quantitatively determine the level of SIV or SHIV viral RNA in plasma of nonhuman primates infected with SIVor SHIV. Assays may include, but are not limited to, bDNA, NASBA, or PCR assays.

Adequacy and suitability of the documented training, experience, scientific expertise, and availability of the Principle Investigator and appropriate scientific staff in performing assays to detect and characterize viral RNA in mucosal tissues or secretions, lymphoid tissue, or other tissue of nonhuman primates infected with SHIVor SIV, with emphasis on the detection of viral RNA in tissue biopsies.

Adequacy and suitability of the documented training, experience and scientific expertise of the Principle Investigator and appropriate scientific staff in developing new or more sensitive assays to quantitatively detect viral nucleic acids in infected animals, in order to maintain the capability of providing state-of- the-art assays under this contract.

Adequacy and suitability of the documented experience of the Principal Investigator in the management, administration, and coordination of a laboratory that has conducted a large number of assays in collaboration with multiple investigators.

Adequacy and suitability of the documented training and experience of appropriate staff in the management of computer data files for storage and retrieval of assay results.

2. TECHNICAL APPROACH/METHODOLOGY **40**

Adequacy, logic, comprehensiveness, and scientific and technical appropriateness of the proposed technical approaches and methodologies to be used to conduct the tasks specified in the Statement of Work. Completeness of description of the proposed methodologies and thoroughness of discussion of potential problems and appropriate controls and alternate approaches to be used to conduct the proposed tasks:

Quantitative determination of the level of SIV or SHIV viral RNA in plasma of nonhuman primates infected with SIV or SHIV. Assays may include, but are not limited to, bDNA, NASBA, or PCR assays.

Detection and characterization of viral RNA in mucosal tissues or secretions, lymphoid tissue, or other tissue of nonhuman primates infected with SHIVor SIV, with emphasis on the detection of viral RNA in tissue biopsies.

Development of new or more sensitive assays to quantitatively detect viral nucleic acids in infected animals, in order to maintain the capability of providing state-of- the-art assays under this contract.

Acquisition, storage, and management of specimens submitted for assay.

Tabulation of assay results and maintenance of computer data files of assay results. Electronic transfer of data to a centralized NIAID-supported database.

Establishment and maintenance of a Quantitative Viral RNA Reference Laboratory capability.

3. RESOURCES AND FACILITIES **10**

Adequacy, suitability, and documented availability of laboratory facilities, resources, and equipment necessary to conduct the specified tasks, including appropriate (at least BSL-2) biocontainment laboratory facilities for conducting work with live, infectious SIV, SHIV, or HIV.

Adequacy, suitability, and documented availability of computer resources for data reporting.

Adequacy and suitability of the Offeror's Safety Plan, including personnel training procedures.

Adequacy and suitability of the plan for a transition to a successor contractor at the end of this contract period.

TOTAL: 100